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A PROPOSAL TO DETERMINE IF THE INCIDENCE OF ORAL MUCOSAL LESION REGRESSION IN AIR FORCE BASIC MILITARY TRAINEES IS ASSOCIATED WITH PRIOR TOBACCO USE HABITS

By

Gary C. Martin, B.A., D.D.S.

APPROVED:

Frank I. Moore, Ph.D.

Jack Hayes, Ph.D.

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THESIS PROPOSAL

Presented to the Faculty of The University of Texas

Health Science Center at Houston

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
SCHOOL OF PUBLIC HEALTH
Houston, Texas
August 1996

Dedicated with love and appreciation to

My wife, Sue

and

My children, Chris, Curt and Marissa

ACKNOWLEDGEMENTS

I wish to express my most sincere appreciation to the faculty and staff of the School of Public Health, San Antonio campus and Major Kevin Grayson Brooks AFB, Texas.

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To my wife, Sue, and our children, Chris, Curt and Marissa, thank you for your love, your support, and your sacrifices that made this endeavor possible.

Submitted: June 28, 1996

DETERMINING IF THE INCIDENCE OF ORAL MUCOSAL LESION REGRESSION IN AIR FORCE BASIC MILITARY TRAINEES IS ASSOCIATED WITH PRIOR TOBACCO USE HABITS

Gary C. Martin, B.A., D.D.S., M.P.H.
The University of Texas
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School of Public Health, 1996

Supervising Professor: Frank I. Moore

Using responses to a health survey administered to all basic military trainees at Lackland AFB, Texas individuals will be identified as current users of smokeless tobacco (ST). Current users of ST will be defined as an individual who has used ST regularly (at least once per day), right up to the point of entering Basic Military Training. Each trainee will receive an oral soft tissue examination to determine if there is an observable oral mucosal lesions (OML). Lesions that are identifiable as aphthous ulcers (canker sores) or oral herpes (cold sores) will not be included as an OML for this study. Those individuals identified with an OML and also meet the case definition as current users of ST will be the population at risk for this study. These individuals will be grouped on the level/grade of

their OML. The level/grade is determined during the clinical oral soft tissue exam using the Greer and Poulsen's classification scheme which has three levels. The basic military trainees are not allowed to use ST during their six weeks of training, which provides a very unique environment for this type of study. At the end of the six weeks each cohort member will be re-examined. The level/grade of the OML will be determined and recorded. This data will be used to determine the incidence of regression of these lesions and the possible association with the type and length of use of ST. Results will be used to educate individuals of the benefits of not using ST. For those who are current users, the regression of a precancerous lesion can be a significant reason for an individual to stop using ST. The findings will be beneficial to the clinician for determining when to biopsy an OML associated with ST use. This study will assist the Air Force to develop and implement a program for ST users similar to the current program for cigarette smokers who enter basic military training. This program will be geared to assist those individuals who have not used tobacco products for six weeks, to maintain this healthier lifestyle for a lifetime.

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AFB	Air Force Base	7
CI	Confidence Interval	14
NIH	National Institute of Health	19
OR	Odds Ratio	14
OML	Oral Mucosal Lesion	3
OMLs	Oral Mucosal Lesions	10
SGO	Surgeon General's Office	19
ST	Smokeless Tobacco	1
UAB	University of Alabama at Birmingham	4
US	United States	1
USAF	United States Air Force	1
UTHSC	University of Texas Health Science Center	19

BACKGROUND

Introduction

The hazards of smoking tobacco, predominantly cigarettes, are well documented as a result of a multitude of scientific research. The campaign to educate the public of these health hazards and assist in the cessation of cigarette smoking is on going. The Government of the United States has become very active recently in attempting to prevent the tobacco companies from targeting adolescents in their advertising and enforcing laws to prevent our youth from developing this addictive habit. The results of these campaigns in reducing the use of tobacco products in general has been moderately successful (Giovino,1994). However, smokeless tobacco (ST) use has seen an alarming increase over the past 25 years, especially in white males age 15-34. The prevalence rate for white males age 18-24 has increased from .7% in 1970 to 7.5% in 1991 (Giovino,1994). The prevalence for use of ST by young white males, grades 7 through 12, in 1989 was 9.14% (Wang, 1994). This is a very dramatic increase. A past U.S. Surgeon General Antonio Novello, alarmed at this increased use of ST by younger persons, stated that we could face an oral cancer problem unless effective steps can be taken to reduce the use of ST (McCann,1993). Maybe the time has come to really address this problem head on and actually ban oral snuff as was done in Great Britain (Raw,1990). As a health care provider in the United States Air Force (USAF) I have a keen interest in this problem of

increased use of ST by young white males. The demographics of the USAF demonstrate that we have a large portion of our active duty population who are white males age 18-30. In my clinical practice as a dentist over the past 12 years I have seen an increase in the numbers of my patients who use ST and the associated oral mucosal lesions. The question is, does use of ST really pose a health hazard?

Review of the Literature

Smokeless forms of tobacco enjoyed wide popularity in the American colonies during the 17th and 18th centuries. As early as 1761, John Hill, an English physician warned that ST had harmful effects. In the late 1800's the germ theory for disease was advanced and chewing and spitting were looked upon negatively. Concurrently, the ability to mass manufacture cigarettes provided a cheap alternative for obtaining tobacco. The smoked forms of tobacco became the common and accepted ways to use tobacco. With the warning from the Surgeon General on the harmful effects of smoking and the limits placed on the tobacco industry for advertising cigarettes, the tobacco companies in the early 1970's increased their advertising and marketing for ST. Many users of tobacco saw ST as a healthier alternative to smoking cigarettes (Goolsby,1992).

There have been several studies that have documented the health risks of using ST on a regular basis. The association between ST use and oral and pharyngeal cancer has been documented (Christen,1992) (Goolsby,1992) (Gupta,1994) (Marwick,1993)

(Nelson,1994) (Wray,1993). Studies reflect an increased incidence of oral cancer among persons using ST, even for those who have used for less than 10 years. The highly publicized case shown by CBS's 60 Minutes in 1985 told of Sean Marsee and his death at age 19 from oral cancer after using ST since the age of 12. There is even a study showing that occupational exposure to tobacco in females increases chromosomal aberrations and risk for cancer (Mahimkar,1995). An increased risk of cardiovascular mortality when adjusted for age is 1.4 for ST users (Bolinder,1994). Other health effects are an increased risk for penile cancer, which could be a good reason to help a young male stop or never use ST (Harish,1995). The oral mucosal lesions that are associated with ST use are leukoplakia and hyperkeratosis which many consider to be pre-cancerous lesions. A recent case control study of 245 male ST users age 15 to 77 found that 78.6% of ST users had an observable oral mucosal lesion (OML) identified during routine dental office visits (Little,1992). The use of snuff is associated with lesions that have a greater variety and severity of epithelial changes than those associated with chewing tobacco (Daniels,1992) (Kaugars,1992). The three leading brands of snuff in the U.S. (Copenhagen, Skoal and Kodiak make up 92% of U.S. market) contain high levels of nicotine and the carcinogen tobacco-specific N-nitrosamines when compared to the 4th and 5th best selling snuff brands, Hawken and Skoal Bandits. The actual levels of nicotine are 11.6 versus 6.96mg/g and for tobacco-specific N-nitrosamines 14.3 versus 6.3μg/g (Hoffman, 1995). The use of snuff is on the increase, especially with the younger males age 18-34 (Giovino,1994). The association with gingival recession is also well documented

(Connolly,1992) (Goolsby,1992). But, there are still those who do not agree with the evidence of ST being a health risk. An oral pathologist at the University of Alabama at Birmingham (UAB), Dr. Rodu, proposes that we encourage those cigarette smokers who can not quit to switch to using ST (Rodu,1994). His reasoning is that ST is associated with fewer and less serious health consequences than is smoking. He has a research proposal that is supported by the administration at UAB as good science. His proposal has generated several letters to editors of health care journals (Nelson,1994) (Summerlin,1994). Some of the questions that are raised are whether this proposal is ethical, using known carcinogens in humans, when safe alternatives exist. Dr. Rodu's assumption that those who switch to ST will decrease their rate of smoking related diseases to that of those who quit using tobacco altogether is questionable. Also, in 1994 there was an incidence of 30,000 oral cancers, and a four fold increase of pharyngeal cancer that is associated with the use of ST, with a five year survival rate of 50% (Marwick,1993) (Summerlin,1994).

The tobacco companies have targeted their ST marketing for adolescent young males and they have been very successful. There are researchers in the US that claim that some tobacco companies deliberately manipulate oral snuff products to addict adolescent ST users (Carnall,1995). Others refer to this as "creative marketing". The use of sports figures promoting the use of ST and the distribution of free samples at various sporting events have been very effective at introducing our youth to a risk for nicotine addiction and an increased risk for oral and pharyngeal cancers. Many schools, campuses and work

places are smoke-free, however, the use of ST is not frequently addressed. Many individuals who used to smoke during these work or school hours, now use ST during these hours, but continue to smoke cigarettes after hours. This combination has the potential to increase the risks for disease. A recent survey of U.S. Naval personnel's tobacco use habits during Desert Storm found that many respondents commented they turned to ST because smoking was prohibited at certain times, such as standing duty (Forgas,1996). Today's U.S. Air Force reflects these recent changes in work places. They have made all work areas smoke-free. The potential for increased use of ST in the USAF is a very likely outcome. The use of ST by air crews is well documented since their environment prohibits smoking in or near aircraft and many have a nicotine addiction from years of tobacco use. The prevalence of ST use in the USAF in 1992 was about 5%, however when adjusted for age 18-24, the prevalence rate for regular users increases to 11% (1992 Worldwide Survey of Substance Abuse and Health Behaviors Among Military Personnel). This is significantly higher than the national prevalence for this age group of 7.5%. The Healthy People 2000 objective is to reduce ST use by males age 24 and under to no more than 4%. To reach this objective health professionals need to be more active in educating patients as to the potential hazards of ST. Health Professionals were identified as the single most important information source on ST by a survey of U.S. Army basic trainees (Kenny,1996).

After a thorough review of the literature there are many areas that need further study to assess how significant a health problem use of ST is in the USAF.

1. We need to determine what the prevalence rate of ST use is in our new recruits and the active duty population.

2. We need to assess the current knowledge level of USAF personnel as to the risks of tobacco products, specifically ST.

3. Using basic trainees who are in a "mandatory" tobacco free setting for 6 weeks allows for a clinical evaluation of ST associated lesions and their response after 6 weeks of not being exposed to ST.

4. Determine what can be done to assist those who have quit using ST during their six weeks of basic training to make this a permanent change. What percentage of those who have quit, start the use of ST again? This topic is currently being addressed and investigated for this population of basic trainees in regards to cigarette smoking. The Principal Investigator is Robert C. Klesges, Ph.D., from the University of Memphis.

Purpose of the Proposed Research

The purpose of this study is to determine if the incidence of oral mucosal lesion regression in Air Force Basic Military Trainees is associated with prior tobacco use habits. One hundred trainees with an OML and recent use of ST will be the subjects for this prospective cohort study. The unique environment of a "mandatory" tobacco free basic

training setting for 6 weeks is very valuable. This environment allows for a clinical evaluation of ST associated lesions and their response after 6 weeks of not being exposed to ST or any other forms of tobacco. Data on the type, length of ST use, original level of the OML and the amount of regression of the OML will be collected, analyzed, interpreted and reported.

The findings from this research could be used to educate individuals on the importance of not using ST. For those who are current users, the regression of a precancerous lesion can be a significant reason for an individual to stop using ST. The findings can also be beneficial to the clinician when determining when to biopsy an OML associated with ST use. One of the long-term objectives is to assist the USAF to implement a program for ST users similar to the current program for cigarette smokers who enter basic training. This program is geared to assist those individuals who have not used tobacco products for six weeks, to maintain this healthier lifestyle for a lifetime.

METHODS AND PROCEDURES

Coordination of Study

This research proposal will be presented to the USAF Clinical Investigative Directorate, Lackland Air Force Base (AFB) for review. Approval for this study is anticipated because the oral examinations and completion of the health survey, that are

required for this study, are currently performed as part of the basic military training process. The Air Force is emphasizing disease prevention and the importance of decreasing the use of tobacco products. This study will provide beneficial information that can be used in these areas of concern. The study will not place the individual at any increased risk. A privacy act statement will be required of each individual in the study. An informed consent will be obtained, however, the study is observational only and does not include any invasive treatment.

Study Strategy

The epidemiologic study method that will be used is a prospective cohort design. Each basic trainee currently completes a health survey with specific questions as to prior use of tobacco products, including the type of the ST product used most frequently. The length of ST use is also determined from the survey. Each basic trainee will receive an oral examination during the first week of basic training. Individuals with an observable OML and meet the definition of a "current user" of ST will be invited to be subjects for this study. The incidence of regression of the subject's OML will be determined by an oral examination at the end of the six weeks of basic military training. Statistical analysis will be performed to determine if the incidence of OML regression is associated with the type of ST used, length of use of ST and the original level of the OML.

An example of testing one of the hypotheses is the null hypothesis that the incidence of regression of an OML is the same for the various types of ST, chewing tobacco vs. oral snuff. The alternate hypothesis is that the incidence of regression of an OML is different for the various types of ST.

Study Population

The community at risk are all USAF Basic Military Trainees at Lackland AFB, Texas. Approximately 250 USAF Basic Military Trainees at Lackland AFB, Texas will be examined each week of the study. Trainees are grouped into flights of 50 individuals and are assigned a specific flight identification number. Preliminary data from the health survey of USAF Basic Military Trainees (Aug 95-Mar 96) indicate that over 90% of ST users are white males under the age of 22. Current users of ST will be identified by responses to question 9 of the health survey and the AF Form 696, Dental Health History. Those individuals identified with an OML and meet the case definition as current users of ST will be the population at risk for this study.

Operational Definitions

A "current user" will be defined as an individual who has used ST regularly (at least once per day), right up to the point that they entered Basic Military Training.

"Presence of oral mucosal lesions" (OMLs) will be determined from the oral examination performed by a dentist. Lesions that are identifiable as aphthous ulcers (canker sores) or oral herpes (cold sores) will not be included as an OML for this study.

"Level/grade of the OML" will be determined using Greer and Poulsen's classification scheme. The three levels are as follows:

- Level I Lesion - Superficial lesion with color similar to that of the surrounding mucosa with slight wrinkling and no obvious thickening.

Level II Lesion - Superficial whitish or reddish lesion with moderate wrinkling and no obvious thickening.

Level III Lesion - Red or white lesion with intervening furrows of normal mucosal color, obvious thickening and wrinkling.

"Regression" of an OML will be defined as a lesion that has healed to a state that upon clinical examination no OML is visible.

"Subject's identification number" is the individual's specific flight identification number and the last six digits of their social security number.

Study Variables

The independent variables will be:

1 - Type of ST used - chewing tobacco versus oral snuff

2 - Length of time ST used - measured in months of use 0-6, 7-12, >12

3 - Level of original lesion - I, II, III

The dependent variable is the regression of the OML at the end of the six week period of no tobacco use. The variable will be classified as follows:

Regression - Yes (Absence of OML)

Regression - No (OML present)

Sample Size

The sample size required for this study will depend on the smallest expected cell frequency for the various 2 x 2 tables. The smallest expected cell frequency should be the Level III lesion with regression. The prevalence rate of ST use in 18-24 y.o. males in the 1992 USAF Health Survey was 11.0%, the national prevalence rate is 7.5%. The use of a conservative prevalence rate of 9% will be appropriate when determining sample size. There have only been a few studies that examined the prevalence of OMLs in ST users, the numbers range from 50 - 78.6%. Again , a conservative prevalence of 50% will be used for determining sample size. If we screen 2,000 recruits, 180 individuals (9%) will be identified as current users of ST, 50 % will have an observable OML. This will give us a total of 90 individuals, that will be grouped (sub-cohort) at an estimate of 36 for Level I (40%), 36 for Level II (40%), and 18 individuals with an OML for Level III (20%). If we are unable to obtain the required number of individuals for each sub-cohort the analysis

may have to be simplified. The sample size is for an alpha of .05 and a power of .80. This sample size should provide the power necessary to detect a difference of 20% or larger in comparing the number of individuals who have regression of their OML with those who don't have regression of their OML.

Data Collection and Processing

The health survey and AF Form 696, Dental Health History, that are completed by all USAF Basic Military Trainees will provide data concerning the type and length of use of ST. These documents contain a privacy act statement that is signed by the individual trainee. The oral examinations will supply the data as to the original level/grade of the OML and again the level of the OML six weeks later. This data is recorded in the individual's dental health record for both examinations and used for determining the amount of regression of the OML. Each study subject must complete the informed consent.

If an individual is examined and the OML is classified as a severe level III, the member will be referred for immediate medical consultation with the Oral Maxillofacial Surgery Department at the Dunn Dental Clinic, Lackland AFB and will not be included in the study. Each individual will have a clinical photo taken of the OML at the initial examination and the subject's identification number will be part of the photo for referencing purposes. Any photos that will be used for publication will have this number

removed. At the end of the six weeks each cohort member will be re-examined. A clinical photo and the level of the lesion will be recorded. Any individual with a lesion that has not resolved at the end of the six weeks will be referred for further medical evaluation. The use of flight number and the last six digits of the social security number will be used to correlate health surveys and the clinical oral soft tissue exam (includes the clinical photo).

The data that has been collected will be entered into a computer data base by each subject's identification number. This data will than be collated and entered into the appropriate 2 x 2 tables for analysis. The data will also be entered to allow for logistic regression analysis because of the possibility that many of the 2 x 2 tables might have cells with values of zero. For this type of analysis data will be coded. For example, regression will be coded 0 = no and 1 = yes, chewing tobacco = 0 and snuff = 1 and length of use 0-6 months = 0, 7-12 months = 1 and >12 months = 2. For the variables length of use and the level of the original OML, two dummy variables, n-1, will be required. The data base will be compatible with the STATA software. The photographs, completed informed consent forms and health surveys will be placed in a locked filing cabinet in the primary investigator's office.

Data Analysis

The incidence of regression of the OML will be determined and the data will be analyzed to determine if there is an association with the type of ST used, length of time that ST was used or the level/grade of the original OML. It will also be possible to determine the prevalence of OMLs in this population of basic trainees and its association with use of ST. The odds ratios (OR) will be calculated for the crude OR , stratum specific OR and will include 95% confidence intervals (CI). Odds ratios will be used as the measure of association to permit multivariate analysis using logistic regression to control for possible confounders.

The data will be analyzed and displayed in tables, figures and graphs as seen in the following examples:

Incidence of Regression of OML = $\frac{\text{Number of individuals with regression of their OML}}{\text{Number of individuals with OML (Total sample size)}}$

Prevalence of OMLs

	OMLYES	OML NO	TOTALS
ST USER	90	90	180
ST NON USER	36	1784	1820
TOTALS	126	1874	2000

Prevalence of OML for ST user = $\frac{90}{180} = .50$

The statistical analysis of the data in the 2 x 2 tables will include the relative risk (RR), crude OR, 95% confidence interval (CI), stratum specific OR, and summary OR

Mantel-Haenszel. The statistical significance will be calculated using the Chi-square test and the Mantel-Haenszel Chi square test.

	REGR NO	REGR YES
SNUFF	a	b
CHEW	c	d

$$\text{Relative risk} = \frac{\frac{a}{a+b}}{\frac{c}{c+d}}$$

Crude OR

$$\text{Odds Ratio} = \frac{ad}{bc} \qquad 95\%\ CI = \exp\left[\ln(OR) \pm 1.96\ \{(1/a) + (1/b) + (1/c) + (1/d)\}^{1/2}\right]$$

Stratum Specific OR

Length of use 0-6 months

	REGR NO	REGR YES
SNUFF	a	b
CHEW	c	d

Length of use 7-12 months

	REGR NO	REGR YES
SNUFF	a	b
CHEW	c	d

Length of use > 12 months

	REGR NO	REGR YES
SNUFF	a	b
CHEW	c	d

$$\text{Summary OR Mantel-Haenszel} = \frac{\sum a_i d_i / t_i}{\sum b_i c_i / t_i}$$

Chi-square test $\qquad X^2 = \dfrac{n\,(ad - bc)^2}{(a+b)\,(c+d)\,(a+c)\,(b+d)}$

$$\text{Mantel-Haenszel Chi-square test} = \left(\left|\sum a_i - \sum E(a_i)\right|\right)^2 / \sum V(a_i)$$

Logistic Regression Analysis

$\log (P/1-P) = B_0+B_1x_1+B_2 x_2+B_3x_3+B_4x_4+B_5x_5$

P = Probability of OML regression = Probability (y = 1)

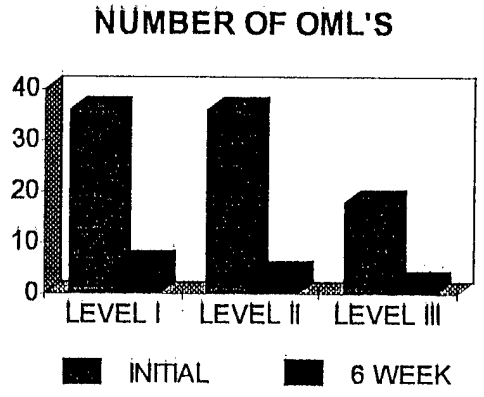
y = regression of OML, 0 = no 1 = yes

x_1 = type of ST 0 = chewing tobacco 1 = snuff

	0-6 months	7-12 months	>12 months
x_2 = Length of use	0	1	0
x_3 = Length of use	0	1	1

	Level I	Level II	Level III
x_4 = Level of original OML	0	1	0
x_5 = Level of original OML	0	1	1

Graph of Potential Results



There are some possible confounders that include previous use of other tobacco products, especially cigarettes, and the use of alcohol. The health survey has questions that are specific to alcohol and cigarette use which will help to control for these confounders by using a multivariate analysis of the data.

Discussion of Possible Study Biases

Self reporting bias is a possibility when using surveys/questionnaires. Individual subjects may intentionally under report behavior such as use of tobacco products. However, these individuals are aware that they will receive an oral examination shortly after completion of the survey. This awareness should decrease the amount of under reporting of tobacco use. Those individuals that do not indicate current use of ST on the health survey are not included in the study even if the oral exam reveals findings indicative of ST use. The result of this bias is the potential for a smaller sample size.

During the six weeks of basic training individuals are not allowed to use any tobacco products. Although there is a possibility that one could still use tobacco products, it seems to be very remote with the constant monitoring during basic training. If an individual subject does use tobacco products this would decrease the amount of regression for the OML.

The potential for misclassification as to the level/grade of the OML is a possibility when more than one dentist is performing the oral examinations. The risk of

misclassification will be reduced by the use of practice sessions. The three dentists will classify the teaching examples of OMLs independently. The results will be compared, and training will continue, until there is an acceptable level of inter-examiner agreement as calculated by using Cohen's kappa statistic.

Implementation

IMPLEMENTATION SCHEDULE AND REQUIRED RESOURCES

TIME	ACTION REQUIRED
Aug 1996	-Request access to smokeless tobacco data supplied by the Population-Wide Smoking Cessation/Prevention Grant (NIH HL 5378; SGO 94-123). -Request support of the Commander of Air Force Basic Training. -Submit application for study authorization to Wilford Hall Medical Center's Clinical Investigation Directorate. RESOURCES Program Manager Copy of thesis proposal
Oct 1996	-Training sessions for dental examiners to standardize the use of the Greer and Poulsen's classification scheme of oral mucosal lesions. -Request assistance of biostatistican assigned to the Community Dentistry Department at the UTHSC, San Antonio for data tabulation and analysis.

TIME	ACTION REQUIRED
	-Obtain clinical camera and film necessary for 200 photographs of subject's oral mucosal lesions.
	-Reproduce 110 copies of the informed consent document.
	RESOURCES
	Program Manager and two dental residents (4 hours)
	Photographic supplies for resident training at Dunn Dental Clinic, Lackland AFB, Texas
	Cannon Copier Dunn Dental Clinic
	UTHSC Biostatistician (2 hours)
Nov 1996	-Initiate oral examinations to enroll 90-100 study subjects
	RESOURCES
	Program Manager (15 hours/week for 8 weeks) and two dental residents (6 hours each/week for 8 weeks)
	Exam supplies (exam gloves, 2x2 gauze, disposable mirrors, tongue blades)
Nov 96 - Mar 97	-Data Collection
	-Collation and tabulation of data by biostatistician

Time	Action Required
	-Six week follow-up oral examination of study subjects
	RESOURCES
	Data collected by the Population-Wide Smoking Cessation/Prevention Grant (NIH HL 5378; SGO 94-123)
	Biostatistician (2 hours/month for 5 months)
	Program Manager (2 hours/week for 8 weeks)
	Dental residents (1 hour each/week for 8 weeks)
	Locked/secure filing cabinet for storage of confidential data
Apr 97	-Data analysis
	RESOURCES
	Program Manager (20 hours/week for 4 weeks)
	Biostatistician (5 hours/week for 4 weeks)
	STATA software (statistical program)
	Multivariate analysis of data collected by the Population-Wide Smoking Cessation/Prevention Grant (NIH HL 5378; SGO 94-123)
May 97	-Interpret and present/publish results
	RESOURCES
	Program Manager

Epidemiologist (consultant)

USAF consultant in Oral Pathology

Administrative assistant

Computer with Microsoft Office Software

The responsibility matrix on the next page is a quick reference for identifying the key tasks of the study and the individuals that are responsible for accomplishing these tasks.

PROJECT NAME						LEGEND
Smokeless Tobacco & Oral Mucosal Lesions						P= Prime
PROJECT MANAGER						S= Support
Dr. Gary C. Martin						
TASK	TASK ID	Dr. G.Martin	Mr Stat	Maj Epi	Dental Res	Admin Assist
Study Authorization from USAF	A	P				S
Access to Smoking Cessation/ Prevention Data Grant NIH HL 5378	B	P				
Training of Dental Examiners	C	P	S		S	
Perform Oral Soft Tissue Exams	D	P			P	
Informed Consent Completed by Study Participants	E	P			S	
Data Collection/Collation/Tabulation	F	S	P		S	
Data Analysis	G	S	P	S	S	S
Interpret & Present Results	H	P	S	S		S
Close Project - Maj Martin	I	P				

Budget Summary

This study will be performed in a military environment using existing resources. The required resources are described in terms of the time necessary for the study. Equipment such as the Cannon copier, computer, printer and the clinical cameras are available to all dental residents at no cost to the resident. Supplies used for the oral examinations are routine stocklisted items that are budgeted specifically for this purpose. Office supplies that will be used during the study such as pens, pencils, and paper are minimal and are readily available. Table I is a summary of the required resources listed by major categories.

Table 1. Budget Summary According to Resource Type

		COST OR TIME REQUIRED	
1.	PERSONNEL		
	a. Project Manager (Principal Investigator)	Half time	40 weeks
	b. Dental Resident #1	7 hrs/week	20 weeks
	c. Dental Resident #2	7 hrs/week	20 weeks
	d. Biostatistician Consultant	2 hrs/month	20 weeks
	e. Epidemiologist Consultant	2 hrs/week	4 weeks
	f. Administrative Assistant	2 hrs/week	40 weeks
	g. Oral Pathology Consultant	4 hrs/week	1 week
2.	OFFICE SPACE		
	a. One Office	Full time	40 weeks
	b. Two Desks and Four Chairs	Full time	40 weeks
	c. Three Drawer Lockable Filing Cabinet	Full time	40 weeks
	d. Adequate Room Lighting	Full time	40 weeks
3.	EQUIPMENT		
	a. Computer/Software	Full time	40 weeks
	b. Printer	Full time	40 weeks
	c. Canon Photocopier	As needed	40 weeks
4.	SUPPLIES		
	a. Oral Exam Supplies	20 weeks	
	b. Office Supplies	40 weeks	
5.	COMMUNICATIONS		
	a. Telephone (Long distance/autovon capable)	Full time	40 weeks
	b. Fax Machine	As needed	40 weeks
6.	TRANSPORTATION		
	a. There are no costs anticipated for transportation purposes.		

DISCUSSION

Merit of Research

This research will provide information that will be valuable in assisting the oral health practitioner in assessing the risks associated with an OML in individuals who use ST. It is quite unique to find a setting where individuals with an OML are required to involuntarily refrain from using tobacco products for six continuous weeks. The findings can also be used in educating the public as to the potential health hazards of using ST and the benefits of stopping the use of ST.

Strengths of Study

The strengths of this study are that we can observe these cohorts in a very unique environment where 90 ST users with an OML will not use any tobacco products, including ST, for six weeks. The access to the individuals in the cohorts for follow-up is excellent and the anticipated numbers of individuals who could be lost during the study are extremely small.

Potential Weaknesses

There are some possible weaknesses of the proposed study method. The potential for recall bias where an individual gives false information on the survey is a reasonable possibility. This will usually be that an individual will under report their use of tobacco products. This possibility will be reduced by the knowledge that each individual will receive an oral examination. The fear that the dentist will be able to determine that the individual does use tobacco products, even though the survey responses indicate to the contrary, should aid in improving the validity of the responses.

The possibility for misclassification of an individual's OML exists because there will be more than one examiner. The use of the Greer and Poulsen's classification scheme will reduce this possibility. The practice sessions for the three dentists that will perform the oral examinations will assist in the standardization of the examiners. These measures will help to reduce the possibility of misclassification.

Expected Results

This study is expected to show that those individuals with the more severe OML (Level III) will have less regression when compared to the group with Level I OMLs. The amount of regression will be associated with the type of ST used. Those individuals who used oral snuff will have less regression of their OML when compared to those individuals

who used chewing tobacco. Finally, those individuals who used ST for more than 12 months will have less regression than those who have used ST for less than 6 months.

CONCLUSIONS AND RECOMMENDATIONS

The results of this study will demonstrate the importance of not using ST. Oral mucosal lesions are strongly associated with the use of ST and this information can be used for educating the population of this increased risk. The regression of a precancerous lesion can be a significant reason for an individual to stop using ST. If a large percentage of the OML's resolve after six weeks, this could reduce the number of biopsies that will be performed along with the associated risks and discomfort. These findings will assist the USAF to implement a program for ST users similar to the one used for cigarette smokers who enter Basic Military Training. Hopefully, this will enable those who have quit using ST during their 6 weeks of Basic Military Training, to maintain this healthier lifestyle for a lifetime.

APPENDIX

INFORMED CONSENT

INVITATION TO PARTICIPATE IN A RESEARCH STUDY

You are invited to participate in a research study entitled: Is The Incidence Of Oral Mucosal Lesion Regression In Air Force Basic Trainees Associated With Prior Tobacco Use Habits. Your decision is voluntary and you may refuse to participate, or withdraw from the study at any time. You may also refuse to answer any questions during interviews. This study has been approved by the Committee for the Protection of Human Subjects of the University of Texas Health Science Center at Houston (CPHS) as HSC-_____.

PURPOSE OF THE STUDY

Approximately 100 basic trainees will be enrolled in this study. Those individuals who used smokeless tobacco regularly up to the point of entering Basic Military Training and have an oral mucosal lesion (mouth sore from using smokeless tobacco) will be invited to participate. This study will allow us to understand how these mouth sores respond when no tobacco products are used for a six week period.

DESCRIPTION OF THE STUDY

All Air Force Basic Military Trainees must complete the health questionnaire and receive an initial oral/dental exam. Those individuals who participate in the study will have a photograph of their oral mucosal lesion at the initial exam and again at the end of the six weeks of training. They will also be asked how long they have used smokeless tobacco and the type of the product they used most. All users of smokeless tobacco are informed of the health risks associated with it's use and the benefits of quitting this harmful habit.

TIME COMMITMENT

The amount of time that will be required for this study is ten minutes at the initial dental visit and twenty minutes at the six week follow-up exam.

TERMINATION OF PARTICIPATION

If any participant voluntarily or involuntarily separates from the U.S. Air Force during the six weeks of Basic Military Training they will be terminated from the study.

BENEFITS

The results of this study will help us to better understand oral mucosal lesions and their response when no tobacco products are used for a six week period of time. This could result in less biopsies of these lesions. A potential benefit is the results could help in the cessation or prevention of smokeless tobacco use and a reduction of the associated health hazards.

RISKS

No risks are foreseen as a result of participation in this research study.

CONFIDENTIALITY/ANONYMITY

The only individual who will have access to identifiable information is the principal investigator. All information will be coded using your flight number and the last six digits of your social security number. Individual names or social security numbers will not be used in reporting of any results for this study.

For further information about this research study or if you have any further questions please contact the principal investigator Lt Col (Sel) Gary C. Martin at (210) 494-2517.

By signing below, you are agreeing to participate in this research study.

Make sure that any questions have been answered to your satisfaction and that you have a thorough understanding of the study. If you have any questions as to your rights as a research subject, call the CPHS at (713) 792-5408. If you decide to participate in this research study, a copy of this document will be given to you.

_____ _____

Subject's Signature Date

_____ _____

Witness/Study Coordinator Signature Date

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VITA

Gary Chadwick Martin was born in American Fork, Utah on August 12, 1956 as the third of four children of Gary and Janice Martin. He graduated from Skyline High School, Salt Lake City, Utah in 1974. He served as a missionary for the Mormon Church in Italy from 1975-77. In 1980 he graduated with a B.A. degree in Sociology from the University of Utah. In 1984 he was awarded his Doctor of Dental Surgery Degree from the University of Washington. He was in private practice for one year prior to entering the U.S. Air Force in August of 1985. He has served as a general dentist at Williams AFB, Arizona and Hickam AFB, Hawaii. He also served as an assistant to the Pacific Dental Commander from 1991-1993. He was selected to be the Dental Education Officer, Directorate of Medical Service Officer Management, Air Force Military Personnel Center, Randolph AFB, Texas in 1993 and performed these duties prior to being selected for a Dental Public Health Residency in 1995. He has been selected for promotion to the rank of Lt. Colonel effective December 1996. His Military awards include the Air Force Achievement Medal with Oak Leaf Cluster, the Air Force Commendation Medal and the Meritorious Service Medal with Oak Leaf Cluster. Dr. Martin is married to the former Sue Simmons of Salt Lake City, Utah. They have three children, Chris (age 16), Curt (age 13) and Marissa (age 11).

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This thesis was typed by the author.